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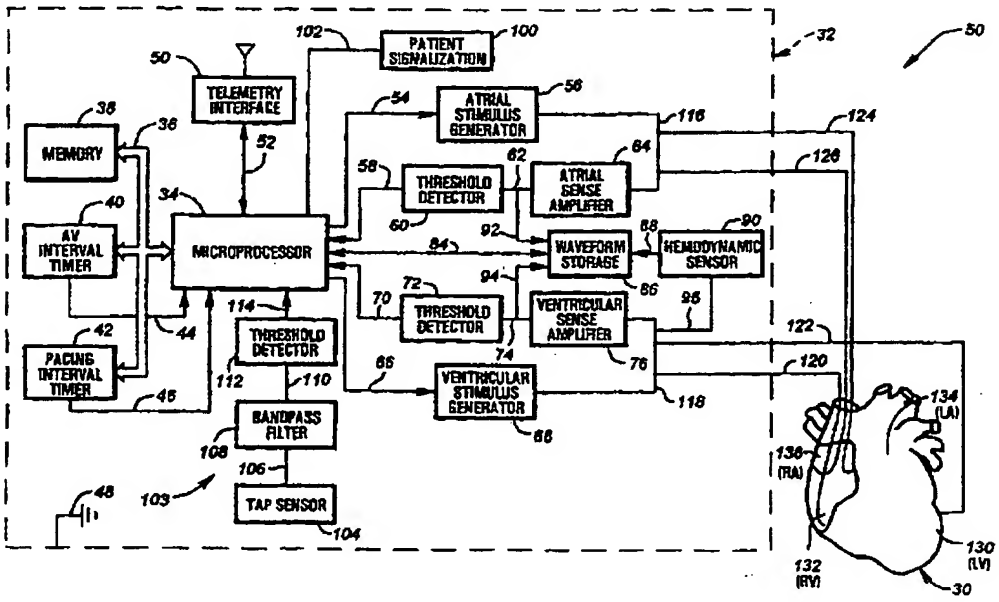

(57) Abstract

An implantable medical device (10) providing bi-directional communication with a patient. The medical device includes a detection circuit (104, 108, 112) for receiving an activation signal that is manually and externally initiated by the patient. This activation signal activates the implanted device to commence diagnostic and/or therapeutic activities. A signalization circuit (100) immediately notifies the patient that such activities have commenced. Data are stored during the activation period and thereafter uploaded to an external programmer for physician evaluation.

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Description

Implantable Medical Device with Confirmation of Patient Activation

Technical Field

The present invention relates to implantable medical devices and particularly to devices which can be activated by the patient using the device, and most particularly to implantable cardiac stimulators such as pacemakers or defibrillators having features or therapies which can be activated by the patient.

Background Art

Modern implantable medical devices perform a large number of diagnostic and therapeutic operations. These operations are programmed into the medical device and are thereafter accessible and modifiable through an external computer based programmer that communicates via telemetry channels. In most cases, a physician performs programming and data retrieval during patient visits after the implant operation. The patient himself typically has no programming control over the diagnostic and therapeutic operations of the implanted medical device.

In some instances though, patients actually have limited control over diagnostic and therapeutic operations. Neurostimulators, for example, may be patient activated to provide treatment for medical, psychiatric, or neurological disorders. In one embodiment, the patient positions a magnet over the implanted stimulator to activate a reed switch. Activation of the reed switch, in turn, initiates a therapeutic mode, such as the delivery of a drug dose or the application of modulating electrical signals to prevent an epileptic seizure.

Other types of implantable medical devices may be patient activated as well. Atrial defibrillators have been proposed to provide a patient activated modality. If the patient experiences a perceived atrial fibrillation, he or she may manually activate the defibrillator. The defibrillator then initiates an appropriate therapy, such as atrial cardioversion, if the atrial fibrillation is confirmed to actually be present.

A patient may activate diagnostic and therapeutic operations of an implanted device with various methods and mechanisms. Such mechanisms include a hand held electronic device that transmits coded commands to the implanted medical device via telemetry channels. In other embodiments, a magnet is placed in proximaty to the implanted device in order to activate a reed switch or magnetic field sensor. In yet other embodiments, the implanted device includes an accelerometer that is capable of recognizing tapping sensations through the skin. The patient simply

taps a specific sequence over the skin of the implanted device to initiate diagnostic or therapeutic operations.

Most implantable devices that employ patient communication are uni-directional. For example, some implantable devices automatically warn the patient of impending events. Cardiac pacemakers, for example, have finite power supplies and are capable of tracking power levels of the implanted battery. When the battery energy falls below a pre-programmed value, the patient is alert to this condition. As another example, implantable defibrillators and cardioverters administer somewhat traumatic shock therapies to the patient's heart. These devices may warn the patient immediately before delivering such a shock.

Implantable devices employing uni-directional patient communication utilize various methods to warn the patient of impending conditions or events. One method is to activate an audible warning, such as periodic beeping sounds. Other methods warn the patient through electrical stimulation of excitable tissue, such as skeletal muscle; and some implanted devices physically vibrate to warn the patient.

In limited circumstances, bi-directional patient communication is necessary for the life or safety of the patient. Implantable devices utilizing this type of bi-directional communication generally require the patient to be notified of impending conditions, and the burden of carrying a supplemental electronic device is justified. The life of the patient, for example, may require an immediate response (such as the correct administration of insulin) or the severity of the therapy sought may endanger the patient (such as the administration of a defibrillating or cardioverting shock).

One important disadvantage with prior patient activated implantable devices is that such devices do not employ appropriate bi-directional patient communication. Once a patient communicates with the implanted device, the patient thereafter does not receive confirmation of this activation. As such, the patient may follow proper procedures to activate the implanted device; yet thereafter, he or she is not assured whether the implanted device properly began to perform the requested operations. Additionally, bi-directional patient communication should be available to a wide array of patients, including those not jeopardized with immediate life threatening conditions.

As a further disadvantage, supplemental devices capable of bi-directional communication have somewhat elaborate circuitry to perform the requisite two-way communication. In this regard, circuitry is required to both transmit a coded telemetry signal and to receive another telemetry signal from the implanted device. The supplemental device must process the received telemetry signals and then provide the patient with adequate notification. It therefore would be advantageous to provide a bi-directional patient communication system that is simple and does not require a complex bi-directional supplemental device.

Further, bi-directional patient communication should not be overly burdensome on the patient.

Disclosure of the Invention

The present invention is addressed to a method and an apparatus for implementing bi-directional communication between an implanted medical device and a patient. Once the medical device is implanted, the patient may manually activate the device to perform diagnostic and therapeutic activity. In the preferred embodiment, the patient taps on his skin located adjacent the implanted device. These tapping sensations initiate an activation signal that causes commencement of the diagnostic and therapeutic activity. The device, in turn, immediately notifies the patient that the activation signal was received and the requested activity began. Preferably, vibrations or electrical stimulation notify the patient. The use of a bi-directional supplemental device, thus, is not required for communication initiated from the patient to implanted device and verification back from the implanted device to the patient.

Once an activation signal is received, the implanted device performs diagnostic activity for an activation period. During this period, data are stored within the implanted device. Thereafter, these data may be uploaded to an external programmer or computer. The data provide important information about the patient and performance of the implanted medical device during the activation period and aids physicians in evaluating the condition of the patient.

The invention, accordingly, comprises the apparatus and method possessing the construction, combination of elements, and arrangement of parts which are exemplified in the following detailed description. For a fuller understanding of the nature and objects of the invention, reference should be made to the following detailed description taken in connection with the accompanying drawings.

Brief Description of Drawings

FIG. 1 is a perspective view of an implantable cardiac stimulator;

FIG. 2 is a block diagram of the cardiac stimulator of FIG. 1 connected to a heart in a multiple-chamber electrode arrangement;

FIG. 3A is a flow diagram of the program structure of the present invention;

FIG. 3B is a flow diagram of the program structure of the present invention;

FIG. 4 is a view of the block diagram of FIG. 2 connected to excitable tissue;

FIG. 5 is the preferred embodiment of a patient signalization circuit of FIG. 2;

FIG. 6 is a block diagram of an alternate embodiment of the present invention; and

FIG. 7 is a preferred embodiment of the magnetic sensor of FIG. 6.

Best Mode for Carrying Out the Invention

FIG. 1 is a perspective drawing of an implantable cardiac stimulator 10. Stimulator 10 is shown as a multi-chamber pacemaker, but the present invention is equally applicable with other active implantable devices, such as cardioverters, defibrillators, neurostimulators, drug delivery devices, cardio-myoplasty devices, devices for treating seizures, and other implantable medical devices. Stimulator 10 comprises a hermetically sealed outer housing 12 having a power supply (not shown) and control circuitry (shown in FIG. 2) enclosed therein. A header portion 14 is attached to housing 12 and has two female electrical connectors 16 and 18 to which leads (shown in FIG. 2) may be mechanically and electrically connected. Leads are commonly used to place stimulator 10 in electrical communication with the heart or other body tissues of a patient. Electrical conductors (not shown) are provided within header 14 and establish electrical connection between electrical connectors 16 and 18 and the control circuitry housed within housing 12. Header 14 additionally includes a signaling electrode, such as an electrically conductive suture point or hole 20.

Turning now to FIG. 2, a block diagram illustrates stimulator 10 connected to a heart 30 in a multiple chamber electrode arrangement. Control circuitry 32 includes a microprocessor 34 that provides control and computational facilities for stimulator 10. Microprocessor 34 has input\output ports connected in a conventional manner via bi-directional bus 36 to memory 38, an interval timer 40, and a pacing interval timer 42. Interval timer 40 and pacing interval timer 42 have an output connected individually via lines 44 and 46, respectively, to a corresponding input port of microprocessor 34. Additionally, an indifferent or ground electrode 48 is provided, and may be connected to housing 12 (FIG. 1).

Although control circuitry 32 is microprocessor controlled, it will be appreciated that other forms of circuitry, such as analog or discrete digital circuitry, can be used in place of microprocessor 34. A microprocessor, however, is preferred for its miniature size and flexibility. Additionally, an implantable medical device having a microprocessor can readily be reprogrammed without additional structural changes. An example of a microprocessor specifically designed for use in pacemakers is fully described in United States Patent Number 4,404,972 entitled "Implantable Device with Microprocessor Control" issued on September 20, 1983 to Gordon et al.

Interval timers 40 and 42 may be external to microprocessor 34, as illustrated, or internal thereto. Additionally, these timers may be conventional up\down counters of the type that are initially loaded with a count value and count up to or down from the count value and output a rollover bit upon completing the programmed count. The initial count value is loaded into interval timers 40 and 42 on bus 36. Respective rollover bits are output to microprocessor 34 along lines 44

and 46. Memory 38 preferably includes both ROM and RAM. Generally, ROM stores operating routines, and RAM stores programmable parameters and variables.

Microprocessor 34 preferably also has an input\output port connected to a telemetry interface 50 via line 52. Stimulator 10, when implanted, is thus able to receive variable and control parameters from an external programmer (not shown) and is able to send data to an external receiver if desired. As such, operating parameters stored within microprocessor 34 may be selectively altered non-invasively. Various suitable telemetry interfaces are known to those skilled in the art.

Microprocessor input\output ports connect via control line 54 to an atrial stimulus generator 56 and via line 58 to a threshold detector 60 and then via line 62 to an atrial sense amplifier 64. Microprocessor input\output ports connect via control line 66 to ventricular stimulus generator 68 and via control line 70 to a threshold detector 72 and then via line 74 to a ventricular sense amplifier 76. Atrial sense amplifier 64 detects the occurrence of P-waves, and ventricular sense amplifier 76 detects the occurrence of R-waves. In addition, pulse data, such as amplitude, width, enable\disable, and pulse initiation codes transmit to atrial stimulus generator 56 and ventricular stimulus generator 68.

Microprocessor input\output ports connect via control line 84 to waveform storage means 86 that is connected via line 88 to a hemodynamic sensor 90. Waveform storage 86 additionally is connected via line 92 to control line 62 and via line 94 to control line 74. Hemodynamic sensor 90 is connected via line 96 to control line 82.

Control circuit 32 additionally includes patient signalization means or circuit 100 connected to microprocessor 34 via line 102 and a detection circuit shown generally at 103. Detection circuit 103 includes a tap sensor 104 connected via line 106 to a band pass filter 108 that is connected via line 110 to a threshold detector 112. Tap sensor 104, band pass filter 108, and threshold detector 112 connect via line 114 to an input\output port of microprocessor 34.

Stimulator 10 is connectable to have a multiple chamber electrode arrangement. FIG. 2 shows a four chamber electrode arrangement connected to heart 30 of a patient (not shown). Ventricular sense amplifier 76 and ventricular stimulus generator 68 are electrically connectable via control line 16 to two leads 120 and 122. Additionally, atrial stimulus generator 56 and atrial sense amplifier 64 are electrically connectable via control line 118 to two leads 124 and 126. Leads 120, 122 and 124, 126 may be connected to electrical connectors 16 and 18 of header 14 (FIG. 1) using bi-furcated Y-connector leads.

Lead 122 is shown as an epicardial type lead that connects to heart 30 at left ventricle 130, and lead 120 is an endocardial type lead that connects in right ventricle 132. In addition, leads 124 and 126 are J-type leads extending into left atrium 134 and right atrium 136, respectively. Those

skilled in the art will recognize that these leads may be in various positions within, about, or adjacent chambers of the heart in order to establish a location for sensing and pacing. Further, various types of leads and methods of lead implantation and fixation also are known. Additionally, although a four lead configuration is illustrated, the present invention may be employed with implantable medical devices having less, more, or no leads.

The overall operating method of the present invention is more fully illustrated in a discussion of the flow diagrams of FIGS. 3A, and 3B. The flow diagrams represent the preferred embodiment of the program structure under which the microprocessor operates. The program structure may be written, for example, in a low level computer language and retained in a memory within the microprocessor.

The flow diagram of FIG. 3A is provided for an implantable medical device that has bi-directional communication capabilities. Such a medical device is able to receive activation signals from the patient and thereafter able to provide the patient with notification that such activation signal was properly received and that patient requested diagnostic and/or therapeutic activity began.

Turning to FIGS. 2 and 3A, the flow diagram begins at block 150. Block 152 shows the pacing program for implantable stimulator 10. The pacing program runs the operations of the stimulator, as shown by line 154 that continually loops back to the pacing program. The pacing program, however, will be interrupted when an input signal or interrupt signal is received, as shown in block 156. In the preferred embodiment, detection circuit 103 initially receives incoming input signals and provides requisite filtering. These input signals pass to tap sensor 104 and then along line 106 to band pass filter 108 and then along line 110 to threshold detector 112 and finally along line 114 to microprocessor 34. The flow diagram then proceeds to block 160 which indicates processing the input signal. The input signal is processed within control circuit 32. Next, block 162 queries whether the input signal is a patient activation signal. Band pass filter 108 and threshold detector 112 filter out selected input signals (such as electromagnetic interferences, noise, erroneous signals, and the like) and enable microprocessor 34 to determine whether such input signals are within a recognizable preselected range of patient activation signals. If the answer to this query is negative, then the flow diagram reverts back along line 164. If the answer is affirmative, then the flow diagram proceeds to block 166 which queries whether to initiate diagnostic and/or therapeutic activity. Generally, microprocessor 34 will initiate either or both diagnostic and therapeutic activity if the input signal is within the preselected range of recognizable patient activation signals. Microprocessor 34 may be programmed such that certain activation signals initiate diagnostic activity, whereas others initiate therapeutic activity. For example, some patients susceptible to epileptic seizures are able to detect the onset of a seizure before detection by an implanted medical

device. At this early detection stage, the patient could communicate with the medical device in order to initiate or modify a programmed seizure therapy, such as the release of an anti-seizure medication. As another example, patients implanted with cardiac stimulation may need to initiate a therapy to more appropriately respond to changes in physical activity.

In some instances, however, diagnostic and therapeutic activity will not be initiated even if the input signal is within this range. For example, microprocessor 34 will not initiate diagnostic and therapeutic activities upon sensing a patient activation signal if such activities are already currently being initiated. If the answer to the query of block 166 is negative, then the flow diagram reverts back along line 168. If, however, the answer is affirmative, then the patient is notified per block 170.

Once diagnostic and therapeutic activity commences, the patient is notified of the commencement of this activity through patient signalization circuit 100 of FIG. 2. Notification confirms to the patient that such activity is under commencement and that the patient activation signal has been received and recognized. Various forms, methods, and mechanisms exist for signaling the patient of this activation and are known to those skilled in the art.

After diagnostic and therapeutic activity commences, microprocessor 34 initiates storage of this activity per block 172. As shown in FIG. 2, microprocessor 34 is connected along line 84 to waveform storage 86. Waveform storage 86 receives analog inputs along lines 92 and 94, and stores the diagnostic and therapeutic activity in RAM memory. In addition, hemodynamic sensor 90 may be an impedance type sensor capable of sensing hemodynamic information about the patient. This information passes to waveform storage 86 along line 88 and is stored therein. After a predetermined activation period, measurable by a time period or information collected, for example, microprocessor 34 terminates diagnostic and/or therapeutic activities as shown in block 174. The flow diagram then reverts back along line 176 to the normal pacing program of block 152.

FIG. 3B shows a flow diagram for uploading data from the implanted medical device. The flow diagram begins at block 180 and then proceeds to the pacing program per block 182. The pacing program runs the operation of the implanted medical device, as shown by line 184 that loops back to the pacing program. The pacing program may be interupted as shown in block 186 indicating service inquire and programming function. As shown in FIG. 2, telemetry interface 50 connects via line 52 to microprocessor 34. Data may be uploaded from or downloaded to microprocessor during, for example, service inquiries, programming operations, or the like. In order to upload diagnostic and/or therapeutic data from the implanted device, block 188 queries whether such data are available. If the answer to this query is negative, the flow diagram loops back along line 190 to the pacing program. If the answer is affirmative, then data may be uploaded, as

shown in block 192. Once data are uploaded, the flow diagram then loops back along line 192 to the pacing program.

A physician, clinician, or health care provider may evaluate the uploaded data in order to aid in determining the health condition of the patient during the activation period in which the diagnostic and/or therapeutic activity was recorded. In the case of an implanted cardiac stimulator, for example, if the patient experiences unusual or suspect cardiac conditions (such as a tachycardia, a bradycardia, syncope, pains, or other types of abnormalities), the patient may activate the implanted medical device to begin diagnostic activities. These diagnostic activities record any of various operations of the medical device and physiological conditions occurring in the patient along with a time stamp indicating the time and date of the event. For example, the medical device may begin to record the intra-cardiac electrograms of the heart of the patient. Diagnostic activity, such as the electrogram, would be recorded during the activation period which may endure, for example, for one or two minutes or for a specific number of heart beats, for example 100 beats. Data are derived during the diagnostic activity and stored in a memory located within the medical device. FIG. 2 shows these data stored in waveform storage 86. Thereafter, these data may be evaluated and examined to aid in diagnosing the cardiac condition of the patient. During a subsequent visit with a physician, for example, the data may be uploaded from the memory in the medical device to an external programmer or computer. The physician may then examine the data and better determine the condition of the patient while he or she experienced the unusual cardiac condition. The data additionally may reveal important information about the operation of the medical device during the activation period.

Turning back now to FIG. 2, detection circuit 103 may have various embodiments. Tap sensor 104, for example, may be an accelerometer, microphone, or like device capable of receiving and transmitting signals to microprocessor 34. Examples of accelerometers and sensors are described in United States Patent Number 4,926,863 entitled "Rate Responsive Cardiac Pacemaker" issued on May 22, 1990 to Alt, and United States Patent Number 4,428,378 entitled "Rate Adaptive Pacer" issued on January 31, 1984 to Anderson et al. Additionally, United States Patent 5,304,206 entitled "Activation Technique for Implantable Medical Device" issued on April 19, 1994 to Baker, Jr. et al fully teaches tap sensing circuits and is fully incorporated herein by reference.

One advantage of utilizing an accelerometer is that an additional, supplemental device is not needed. The patient simply taps on his or her skin located adjacent to the implanted medical device. The control circuitry is capable of distinguishing preselected tapping sequences. If a preselected tap sequence is received, the microprocessor will initiate diagnostic and/or therapeutic activity. Thereafter, the patient will be notified of the initiation of this activity.

FIG. 4 shows one embodiment for notifying a patient that diagnostic and therapeutic activity has commenced. As shown in FIG. 1, cardiac stimulator 10 may be provided with a signaling electrode, such as at least one electrically conductive suture hole or point 20. In FIG. 4, suture point 20 is electrically connected via line 200 to control circuitry 32 and to patient signalization circuit 100. Suture point 20 provides a location that may be attached to excitable tissue shown at 202. Excitable tissue 202 may be, for example, skeletal muscle, a nerve ending, or other tissue capable of perceiving physiological reaction in response to electrical stimulation. In order to notify the patient, an electrical stimulating pulse passes through suture point 20 and to tissue 202 of the patient. This stimulating pulse, in turn, excites tissue 202. The patient then perceives this excitation as a tingle or tickling type sensation and is thus notified of the activation of diagnostic and therapeutic activity.

FIG. 5 shows a shunt circuit 210 as one embodiment of patient signalization circuit 100 of FIG. 2. Shunt circuit 210 comprises an input line 212 connected directly to an output 214 for suture point 20 (FIG. 1) and to a semi-conductor controlled rectifier or SCR 216 or other suitable solid state device or switching means. A Zener diode 218 trips SCR 216 whenever a pulse amplitude exceeds a threshold voltage value of diode 218. Current flow through diode 218 operates to open SCR 216 to current flow. A biasing resistor 220 maintains SCR 216 in an open state for a brief period of time dependant on the component values. Resistor 220 further reduces the sensitivity of SCR 216 to current passing through Zener diode 218 even while the diode is operating at its threshold voltage. Careful selection of the operating parameters of SCR 216 and diode 218 can reduce the need for resistor 220. In addition, a small value capacitor 222 is shown to filter voltage transients that may cause shunt circuit 210 to trigger erroneously. So long as the output voltage of cardiac stimulator 10 (FIG. 1) remains below the breakdown voltage of diode 218, then current will be directed towards the cardiac electrodes. Whenever patient notification is required, however, the microprocessor will increase the output voltage to a level in excess of the breakdown voltage. Zener diode 218 will be conductive and SCR 216 will open. Thereafter, a portion of the stimulating pulse will be passed to suture point 20 (FIG. 1) or other signaling electrode and thus cause excitation of adjacent tissue. In this implementation, the input to shunt circuit 210 is the output from one of the stimulus generators of FIG. 2, for example atrial stimulus generator 56.

As an alternative to shunt circuit 210 of FIG. 5, patient signalization circuit 100 may be provided as a solid state single pole double throw switch. The microprocessor would be electrically connected to this switch to provide control. When the patient is to be notified, the microprocessor would temporarily disconnect one of the leads and establish an electrical connection directly to the signaling electrode. Thereafter an electrical stimulating pulse may be directed directly to the suture

point and adjacent tissue. The throw switch may be mounted within either the housing or the header of the cardiac stimulator. Additionally, any one of various solid state throw switches known to those skilled in the art may be employed to activate the necessary switching.

As another alternative embodiment, patient signalization circuit 100 may be provided as a stimulus generator. The output of the stimulus generator would be connected directly to the conductive suture point. The stimulus generator would be capable of generating a small electrical excitation signal. When the patient is to be notified, the microprocessor would activate the generator to produce an excitation signal at the signaling electrode location and thus excite the tissue and notify or warn the patient of the initiation of diagnostic and/or therapeutic activity.

As yet another embodiment, patient signalization circuit 100 may be provided as a vibrational type circuit. The vibrational circuit would be connected to and activated by the microprocessor. When the patient is to be notified, the microprocessor would activate the vibrational circuit to vibrate the implanted medical device. The vibrations of the medical device would notify the patient that diagnostic and/or therapeutic activity began.

FIG. 6 shows an alternate embodiment detection circuit 103 (FIG. 2). In this embodiment, an external magnet 230 is used to initiate a patient activation input signal to the microprocessor. Magnet 230 is placed over skin 232 and adjacent to and in close proximity with control circuit 32 (FIG. 2) of the cardiac stimulator. Control circuit 32 includes the addition of a magnetic sensor 234 and a conditioning circuit 236 that is electrically connected to microprocessor 34 (FIG. 2). Magnetic sensor 234 may be any appropriate sensor capable of sensing a time varying magnetic field, and is preferably a GMR sensor. Other resistive type sensor geometries are equally applicable to the present invention so long as such resistive sensors are sensitive to a magnetic field.

FIG. 7 shows a possible embodiment for magnetic field sensor 234. Sensor 234 includes a bridge circuit 238 having four bridge elements R1, R2, R3, and R4. Bridge circuit 238 provides an output signal to conditioning circuit 236 via lines 240 and 242. Conditioning circuit 236 demodulates the output signal and provides filtering and signal shaping. The output signal, once conditioned in circuit 236, is then sent to microprocessor 34 (FIG. 2). Conditioning circuit 236 also may define a minimum threshold level from magnetic sensor 234 in order to eliminate erroneous effects of magnetic noise.

Bridge elements R1-R4 of bridge circuit 238 are preferably integrated circuit field effect transistors that have been biased to operate in the resistive region. Two of the bridge elements, for example R3 and R4, are shielded against magnetic influence, as shown by dashed lines 244, while R1 and R2 are unshielded. In the presence of a magnetic field, the output voltage of sensor 234 is independent of the polarity of the magnetic field but depends upon the absolute value of this field.

Magnet 230 may be any one of various supplemental type devices capable of generating a magnetic field. Magnet 230 for example may be a transmitter having power coils that generate a time varying magnetic field or a permanent type magnet.

As an alternative to FIG. 6, other types of supplemental electronic devices may be utilized with the present invention to communicate with the control circuit. For example, electronic devices capable of transmitting coded signals that are received and recognized by the telemetry interface (FIG. 2) are known to those skilled in the art. The present invention, however, does not require an electronic supplemental device that itself performs bi-directional communication. Uni-directional supplemental devices may be employed with the present invention.

WHAT IS CLAIMED IS:

Claim 1. A cardiac stimulator [10] implantable within a patient, comprising:

an outer housing [12] having a header portion [14];

a control circuit [32] enclosed within said housing, and capable of initiating diagnostic activity upon receiving a patient activation signal initiated by said patient;

at least one implantable electrode [120, 122, 124, 126] having a first end mechanically connectable to said header portion and electrically connectable to said control circuit, and a second end for delivering a therapy to the heart of said patient;

a detection circuit [104, 108, 112] within said control circuit for receiving said patient activation signal initiated by said patient; and

a signalization circuit [100] within said control circuit for notifying said patient when said control circuit receives said patient activation signal and thereafter initiates said diagnostic activity.

Claim 2. The cardiac stimulator of claim 1 further comprising a memory [38] within said control circuit for storing said diagnostic activity.

Claim 3. The cardiac stimulator of any of the foregoing claims in which said detection circuit further includes a tap sensor [104], a bandpass filter [108], and a threshold detector [112].

Claim 4. The cardiac stimulator of any of the foregoing claims in which said signalization circuit provides an electrical stimulation to said patient immediately after said control circuit initiates said diagnostic activity.

Claim 5. The cardiac stimulator of any of the foregoing claims is which:

said patient physically taps on an area adjacent said outer housing in order to initiate said activation signal; and

said signalization circuit immediately notifies said patient after said control circuit processes said activation signal.

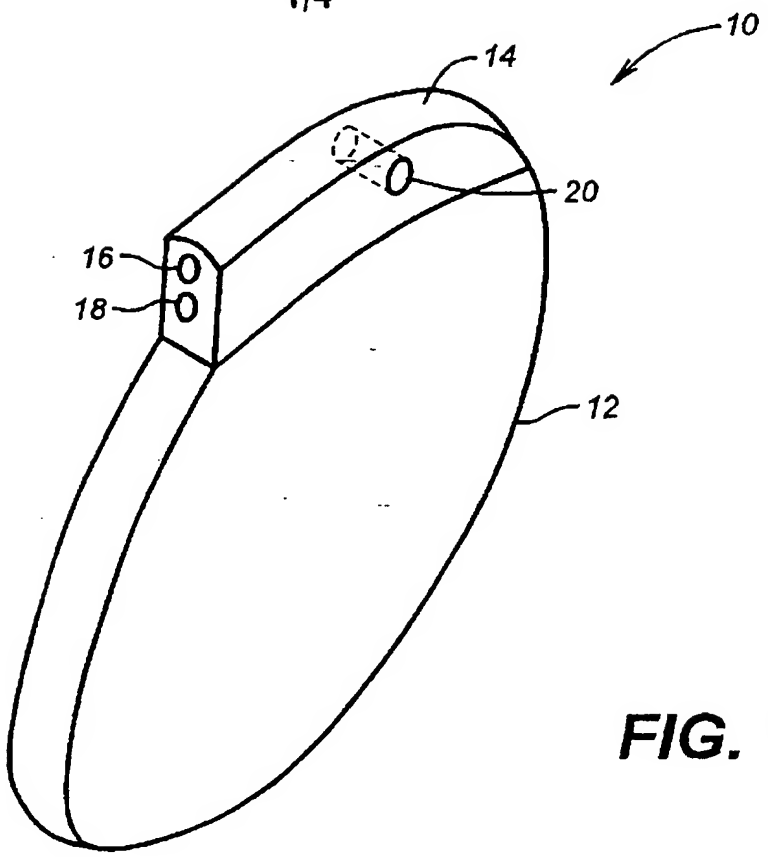

10
14
20
16
18
12

FIG. 1

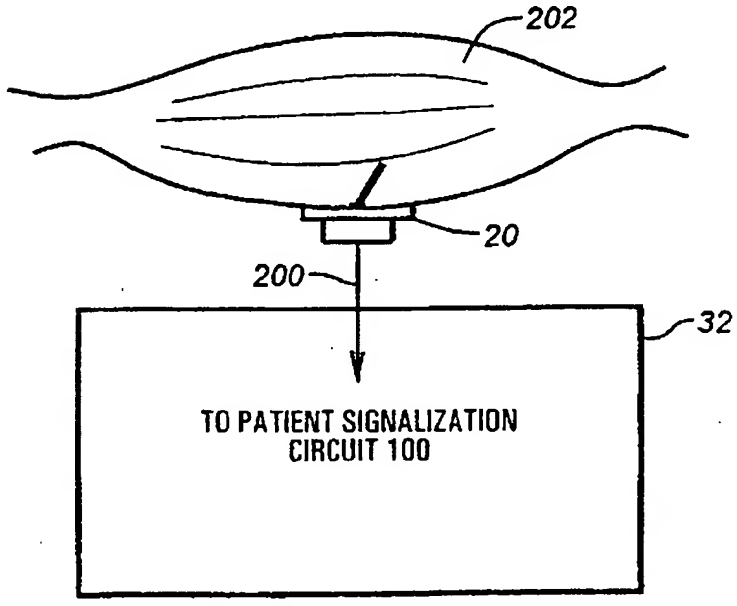
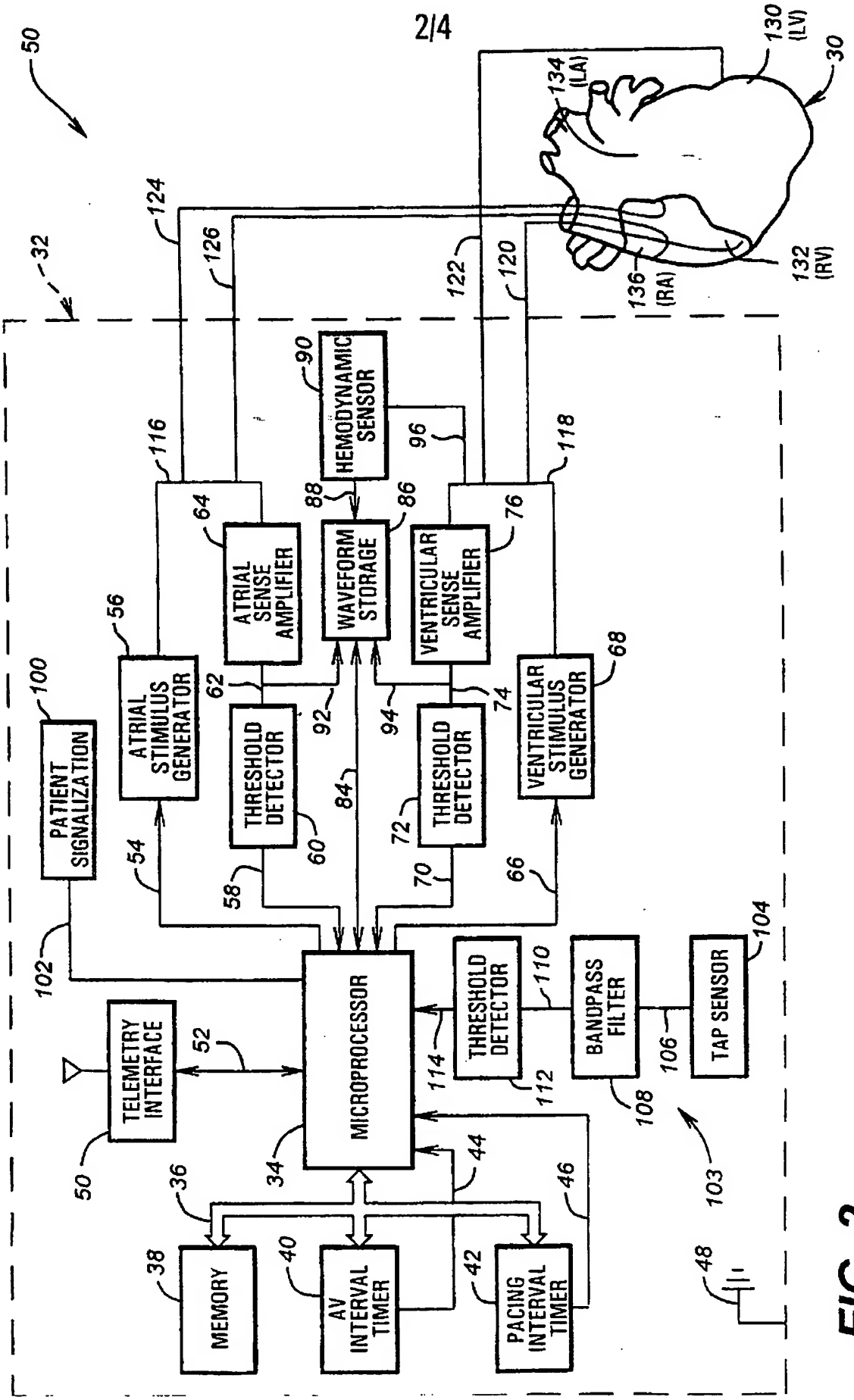

202
20
200
32
TO PATIENT SIGNALIZATION
CIRCUIT 100

FIG. 4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HEMODYNAMIC SENSOR
96
88
86
64
76
ATRIAL SENSE AMPLIFIER
WAVEFORM STORAGE
VENTRICULAR SENSE AMPLIFIER
56
68
100
ATRIAL STIMULUS GENERATOR
VENTRICULAR STIMULUS GENERATOR
PATIENT SIGNALIZATION
62
92
94
74
THRESHOLD DETECTOR
THRESHOLD DETECTOR
84
60
72
54
58
70
66
102
MICROPROCESSOR
114
THRESHOLD DETECTOR
110
BANDPASS FILTER
104
TAP SENSOR
TELEMETRY INTERFACE
52
112
106
108
50
34
44
103
36
46
38
40
42
48
MEMORY
AV INTERVAL TIMER
PACING INTERVAL TIMER

FIG. 2

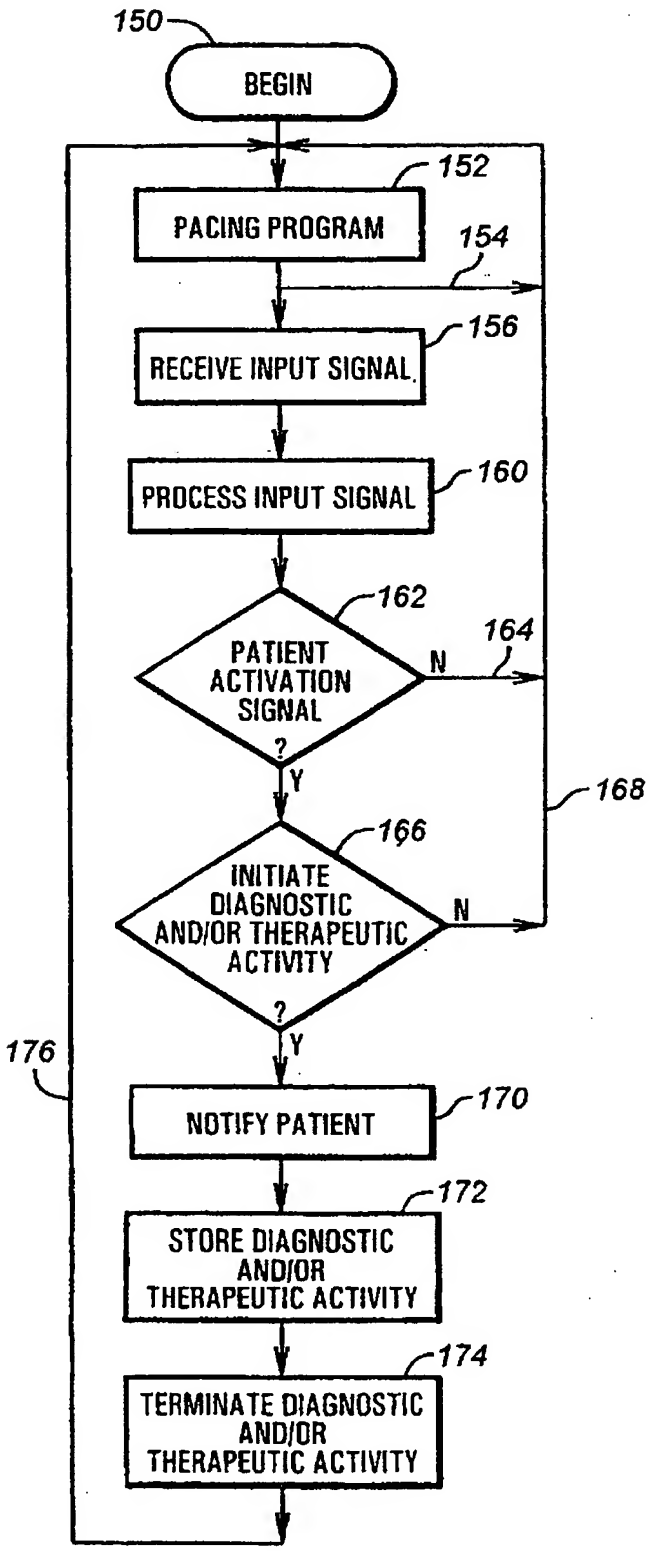
150
BEGIN
152
PACING PROGRAM
154
156
RECEIVE INPUT SIGNAL
160
PROCESS INPUT SIGNAL
162
PATIENT ACTIVATION SIGNAL
?
N
164
Y
168
166
INITIATE DIAGNOSTIC AND/OR THERAPEUTIC ACTIVITY
?
N
Y
176
170
NOTIFY PATIENT
172
STORE DIAGNOSTIC AND/OR THERAPEUTIC ACTIVITY
174
TERMINATE DIAGNOSTIC AND/OR THERAPEUTIC ACTIVITY

FIG. 3A

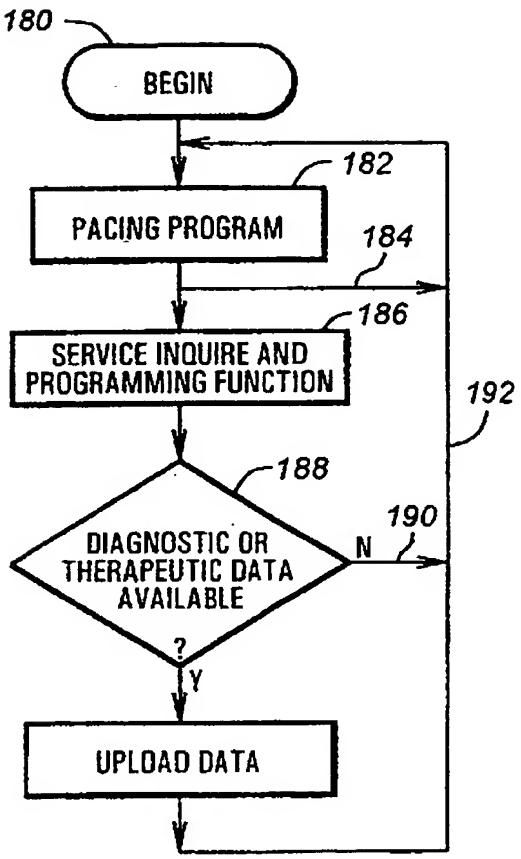
180
BEGIN
182
PACING PROGRAM
184
186
SERVICE INQUIRE AND PROGRAMMING FUNCTION
192
188
DIAGNOSTIC OR THERAPEUTIC DATA AVAILABLE
?
N
190
Y
UPLOAD DATA

FIG. 3B

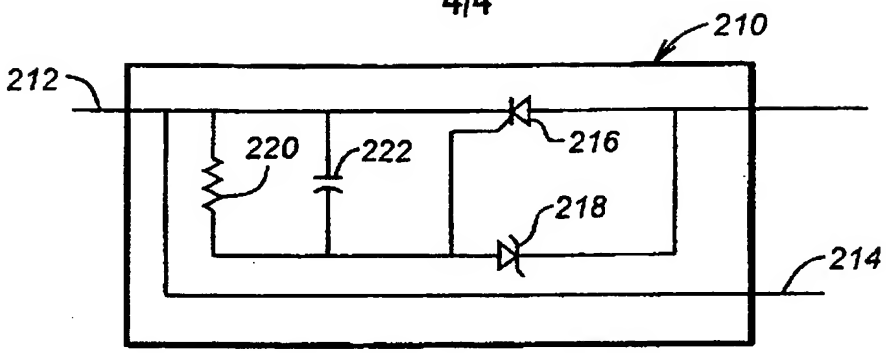

FIG. 5

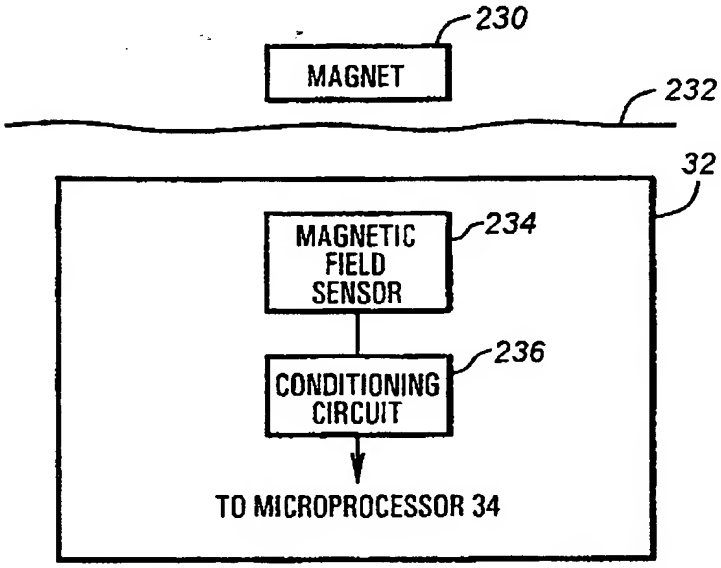

FIG. 6

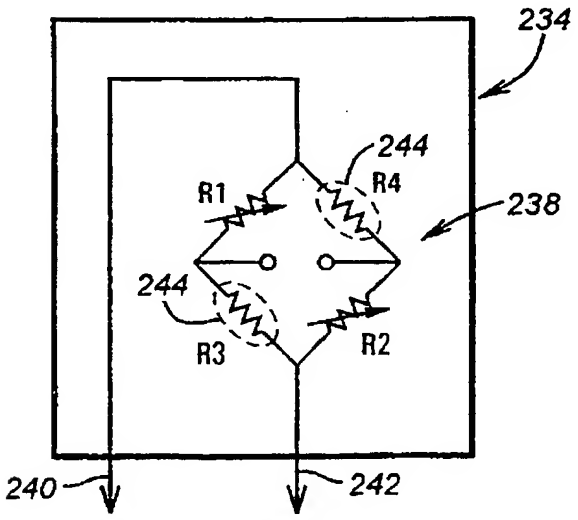

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/07851

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/372

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 195 09 609 A (SIEMENS ELEMA AB) 26 October 1995 see abstract; figure	1-3,5
Y	---	4
Y	US 5 076 272 A (FEREK-PETRIC BOZIDAR) 31 December 1991 see abstract	4

A	US 4 545 380 A (SCHROEPPEL EDWARD A) 8 October 1985 see the whole document	1,2,5

A	US 5 304 206 A (BAKER JR ROSS G ET AL) 19 April 1994 cited in the application see the whole document	1,2,4

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
19 August 1997	26. 08. 97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	**Authorized officer** Ferrigno, A

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/07851

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 140 131 A (DUTCHER ROBERT G ET AL) 20 February 1979 see abstract; figures	1,4

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US 97/07851

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